

## REMARKS

Claims 34 to 38 remain in the application and stand rejected. Applicants are grateful to the Examiner for the telephone interview of December 30, 2010, wherein claim 34 and references Ash et al and Cianci were discussed although no agreement was reached; correction of certain reference numeral errors in paragraph [0057] were agreed upon. In the Examiner's Interview Summary, Applicants' representative does not recall that new reference Consalvo was identified by the Examiner.

Applicants note appreciatively that the Examiner has withdrawn all previous grounds of rejection.

Claim 36 is amended to overcome the rejection thereof under Section 112, second paragraph. The Specification has been amended at paragraph [0057] in accordance with the Examiner's recommendation.

References Raulerson and Cianci have been discussed and distinguished in previous responses.

Reference Consalvo sets forth a dual flow cannula set, wherein a metal needle device is provided with two tubes, with each tube being connectable to respective tubes of a hemodialysis apparatus for performing dialysis on a patient. Figure 7 of the reference depicts the metal needle device injected into a patient at a fistula of the patient's vasculature. The distal end portion of the needle device is injectable into fistula 20 sufficiently far for a side port of a second tube to be within the fistula for withdrawal of blood, while the dialysed blood is returned to the blood by way of a distal tip opening of the first tube, which extends farther along the vein past the side port. The proximal end of the metal needle device separates for being joined to respective tubes, with lengths of Tygon tubing placed around the Y-site and a portion of each diverging portion, for sealingly receiving fittings on the distal ends of the tubes of the hemodialysis apparatus. The reference discloses at column 7, lines 5 to 25, that the lengths of Tygon tubing 14, 15, 16, 17 and 18 are cemented in place to the Y-site at the proximal end of the metal needle device when the needle device is being manufactured.

Respectfully, Applicants traverse the characterization of the disclosure in reference Consalvo presented in the Office Action. The reference does not disclose an implantable catheter, nor subcutaneous tunneling, nor a releasable hub, and the reference fails to disclose that the practitioner selects the site for a hub or secures the hub to the needle device.

The hub of the present invention is attachable to the catheter by the practitioner at a site selected by the practitioner along continuous lengths of the first and second proximal catheter portions, not at their ends. Within the hub, the catheter portions will be disposed in respective channels. Portions of the first and second catheters coextend separately but adjacently in a direction distally from the single distal exit of the hub, while other portions thereof extend continuously proximally from the distally extending portions, separately and spaced apart from each other through the hub and extend proximally from respective exits of the hub. As a result, none of the fluid flowing through the catheter portions within the hub, comes into contact with the hub, and sealing within the hub is unnecessary, unlike in references Consalvo and Raulerson.

The Office Action continues to cite *In re Hutchison*, as support for holding that the phrase in claim 34 “adapted to be releasably attachable by a practitioner” carries no patentable weight. Applicants submit that the holding in this case is limited by the ruling in *In re Venezia* which holds that “adapted” may indeed have structural significance that must be given patentable weight.

Regarding the rejection of claim 34, reference Consalvo fails to disclose an implantable catheter assembly and fails to disclose that a practitioner assembles a hub to a catheter assembly at a site selected by the practitioner. Reference Cianci fails to disclose two lengths of catheter tubing extending from distal end portions through the hub to proximal end portions proximally beyond the hub; only one tubing length extends distally from the hub, although two proximal tubing portions extend proximally therefrom. Reference Raulerson fails to disclose a releasably coupleable hub securable to two catheter lengths by the practitioner. The combination of these references is not supported by a clear line of reasoning supported by rational underpinnings, nor does the Office Action provide a basis for an artisan of routine skill to have a reasonable expectation of success to make the combination. Instead, the combination is the result of impermissible hindsight reasoning by the Examiner after having read Applicants’ application. Therefore, Applicants respectfully traverse the combination and the rejection.

Claims 35 to 38 depend from claim 34, which is believed to patentably distinguish over the references, and therefore, claims 35 to 38 are believed patentable.

The claims are believed to distinguish patentably over the prior art, and allowance thereof is respectfully urged. No new matter has been entered hereby. If any additional fees are due, please charge same to Deposit Account No. 50-2434.

Respectfully Submitted,

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Date

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